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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/774,345

02/06/2004

David H. Cole

V-018-C2

5284

7590 11/14/2007  
JEFFREY J. HOHENSHELL  
710 MEDRONIC PARKWAY  
MINNEAPOLIS, MN 55432

EXAMINER

WOO, JULIAN W

ART UNIT

PAPER NUMBER

3773

MAIL DATE

DELIVERY MODE

11/14/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/774,345

Applicant(s)

COLE ET AL.

Examiner

Julian W. Woo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 47-64 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 47-50, 52, 53, 55-57, 60, 61, and 63 is/are rejected.
- 7) ☒ Claim(s) 51, 54, 58, 59, 62, and 64 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 10/19/07.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Response to Amendment*

1. The finality of the Office action of August 1, 2007 is hereby withdrawn in view of new grounds of rejection presented below.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
3. Claims 47-50, 52, 53, 55-57, 60, 61, and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spence et al. (6,565,581). Spence et al. disclose the invention substantially as claimed. Spence et al. disclose, at least in figures 4-16 and in col. 14, lines 3-8 and col. 19, line 24 to col. 21, line 26; a method for forming a port in a first hollow body (A<sub>1</sub>) having a lumen or for forming an anastomosis or for coupling lumens of first and second hollow bodies, where the method includes forming an opening in a wall of the first hollow body, providing a first securing or coupling

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component (92) capable of producing a magnetic field (i.e., the component may be formed of a metallic material that is inherently capable of producing a magnetic field, when exposed to an external magnetic field), and solely coupling the first securing component to the first hollow body by a mechanical attachment (at 62) to form a port in the first hollow body, where the mechanical attachment has an expandable structure that is in a collapsed condition (see fig. 15) when it is introduced through the opening in the wall of the first hollow body (i.e., element 66 is introduced into the opening via the wall of the hollow body) and is expanded to engage the wall of the first hollow body (see fig. 16), where the method further includes forming an opening in a wall of a second hollow body ( $G_1$ ), providing a second securing or coupling component (94) capable of being attracted by a magnetic field, joining the second securing component to a second hollow body, coupling the second securing component to the port in the first hollow body to form an end-to-side anastomosis or a side-to-side anastomosis, where the expandable structure comprises a plurality of arms (62) that are generally coplanar for contacting the wall of the first hollow body, and where the first and second securing components has a laminated structure and includes a layer of biocompatible material (40).

However, Spence et al. do not explicitly disclose that the first securing component comprises a magnetic material, and that the first securing or coupling component is magnetically coupled to the second first securing or coupling component. Nevertheless, Spence et al. disclose, in col. 40, lines 36-61, that docking extensions or legs (e.g., 70) of the components may be coupled with "magnetic docking legs," among

other forms of coupling. Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the first securing component, so that it comprises a magnetic material, or the first and second securing or coupling components, so that they are coupled magnetically. Such modifications would not only allow coupling of the components, the magnetism of the components would allow convenient alignment of the components and the openings of the hollow bodies.

***Allowable Subject Matter***

4. Claims 51, 54, 58, 59, 62, and 64 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

5. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record, alone or in combination, discloses a method for forming a port in a first hollow body or for forming an anastomosis or for coupling lumens of first and second hollow bodies, where the method includes forming an opening in a wall of the first hollow body, providing first and second securing or coupling components capable of producing a magnetic field, coupling the components to first and/or second hollow bodies via an expandable structure of each of the components, where the structure includes a plurality of self-expanding arms. The prior art of record also does not disclose that the abovementioned method includes releasing the expandable structure from a delivery device adapted to retain the structure in a collapsed condition, where the structure is allowed to expand upon its release.

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As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).


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**Conclusion**

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Julian W. Woo  
Primary Examiner

November 8, 2007